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10/790,640	03/01/2004	Michael D. West	75820.026014	9766

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EXAMINER	
BERTOGLIO, VALARIE E	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,640	WEST ET AL.	
	Examiner	Art Unit	
	VALARIE BERTOGLIO	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06/10/2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,10-12,14-16,21-25,27-36 and 106* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,10-12,14-16,21-25,27-36 and 106* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/2011*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

. Applicant's submission filed on 11/24/2010 has been entered.

The instant application is a continuation of USSN 09/527,026, now abandoned.

Claim Objections

Claims 1,8,25,27,29 are objected to because of the following informalities:

The claims contain multiple "periods" as punctuation.

MPEP § 608.01(m) states that, "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except for abbreviations. See *Fressola v. Manbeck*, 36 USPQ2d 1211 (D.D.C. 1995)."

Claim 29 is objected to because of the following informalities:

A "," should be inserted between "teratoma" and "embryo" at line 2.

Appropriate correction is required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting

ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1,3-8,10-12,14-16,21-24,29-36 remain provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 87-92,94-117 of copending Application No. 11/079,930. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the claims of '930 are not specifically drawn to mammals, the instant claimed methods utilizing reprogramming of somatic cell nuclei by nuclear transfer were notably used in mammalian species. Thus, the generic claimed "cell" in '930 renders obvious the instant claimed mammalian cell..

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant previously requested that this rejection be held in abeyance until otherwise allowable subject matter is identified, at which time, the filing of a TD will be considered.

Claim Rejections - 35 USC § 112-1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1) The previous rejection of claims 1,3-4,6-8,11-12,14-16,21-25,27-36 and under 35 U.S.C. 112, first paragraph, because the specification, is withdrawn in light of Applicant's amendments to the claims

2) Claims 1,3,4,6-8,11,-12,14-16, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method using non-primate, mammalian cells, does not reasonably provide enablement for the claimed method using any mammalian cells other than non-primate mammalian cells. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). The court in Wands states: "Enablement is not precluded by the necessity for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue experimentation. The key word is 'undue,' not 'experimentation.' " (*Wands*, 8 USPQ2d 1404). Clearly, enablement of a claimed invention cannot be predicated on the basis of quantity of experimentation required to make or use the invention. "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." (*Wands*, 8 USPQ2d 1404). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

Claims 1,3,4,6-8,11,-12,14-16 are drawn to a method of nuclear transfer using a near senescent or senescent donor cell of any type to form a blastocyst, isolation of a whole or part of the developing blastocyst, formation of a teratoma with said blastocyst whole or part, and isolation of a cell from the teratoma to obtain a cell with increased remaining populations compared to the donor. Claims now limit the donor to a fibroblast. However, upon further evaluation of these claims, it is noted that the claims require the

production of blastocyst stage primate embryos from which cells are isolated to form a teratoma. This breadth is not enabled.

The specification provides examples for the production of a cell using nuclear transfer methodology. CL53 bovine fetal fibroblast cells were passaged until 95% of their lifespan was completed: The CL53 cells were used to reconstitute bovine oocytes (page 30) and grown to result in a live born calf. Measurement of proliferative life of cells from a cloned fetus and the original donor fetus were compared and demonstrated that the proliferative life of the clone is reset (page 32). Telomere length was also demonstrated to be restored (page 33). The specification teaches that the resulting cell has increased telomere and telomerase activity.

These embodiments are not enabling because of the art-recognized inability to clone primates. Vogel (**Science**, 300:225 and 227, 2003) state that Rhesus monkey NT-generated embryos seemed normal at their early stages but were unable to develop further when implanted into a surrogate mother. This was because the cells had the wrong number of chromosomes, and that this aneuploidy resulted in the abortion of the fetus. This was found to also be the case with human NT embryos. See p. 225. Simerly *et al.* (**Science**, 300:297, 2003) state that, "Primate NT appears to be challenged by stricter molecular requirements than in other animals ... With current approaches, NT to produce embryonic stem cells in nonhuman primates may prove difficult – and reproductive cloning unachievable." See p. 297, 3rd column, last sentence. Additionally, Simerly *et al.* (**Dev. Biol**, 276: 237-252, 2004) teaches that, "As previously reported in NHPs, few SCNT embryos (<1%) developed to blastocyst stage. Here, despite SCNT embryos appearing morphologically normal, many NT constructs generated by aspirated enucleation still demonstrate anueploidy. DNA missegregation is already prevalent by first mitotic telophase, as evident by lagging

chromosomes and loosely organized DNA at the spindle poles ... As development proceeds to the 8-cell stage, monastral interphase microtubule patterns either lacing DNA or with inappropriate chromosomes are observed." See p. 242, col. 1, 2nd full ¶ and Figure 2. Simerly teaches that:

> "Taken together, the data suggest that meiotic spindle removal depletes the egg cytoplasm of HSET, a vital protein for first mitotic spindle pole formation. Also the residual NuMA, retained within the oocyte's cytoplasm following spindle extrusion and imported into the interphase nucleus following SCNT, is not effectively targeted to the spindle poles in mitotic constructs or is below threshold concentrations, perhaps indicating interference with mechanisms that recruits NuMA to the microtubule minus-ends (Compton, 1998)." See p. 248, col. 1, 1st ¶.

Mitalipov (Methods in Mol. Bio, 348: 151-168, 2006) is post-filing art that reviews the state of the art of primate nuclear transfer. They state that, "We were initially successful in producing monkeys by NT using embryonic blastomeres as the source of donor nuclei and have repeated that success. However, when somatic cells are used as nuclear donor cells, the developmental potential of monkey SCNT embryos is limited, and somatic cell cloning has not yet been accomplished in primates." See p. 151, Summary). They further state that, "Remarkable progress in mammalian cloning has been achieved in the past several years. However, somatic cell cloning has not yet been accomplished in primates ...."The developmental potential of SCNT monkey embryos has been limited, seldom progressing beyond the eight-cell stage in vitro." See p. 152, paragraphs 2-3.

3) Claims 21-25,27-28 and 106 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 21-25,27-36 and 106 are drawn to methods involving genetic alteration of cells and use of the cells to make nuclear transfer embryos and cells that comprise the genetic alterations. It appears methodology necessary to enable the claims may be missing.

Claims 21 and 22 require obtaining a mammalian fibroblast (i.e. primary cell), genetically altering the fibroblast wherein the fibroblast is passaged to senescence or near senescence and the cell is rescued from senescence by nuclear transfer and isolation of a 'rejuvenated' cell comprising the genetic alterations. This way, a genetic alteration can be made, the cell can be rejuvenated and altered again and the process repeated. However, the claim recites at lines 3-4 "using nuclear transfer of the mammalian primary cell". The primary cell, however, is only present in the method for the first genetic manipulation and nuclear transfer. After this first nuclear transfer, a new and different cell is isolated such that it is no longer referred to as "said primary cell". Furthermore, the claim fails to recite any methodology relating to what cell is obtained for use in the second and subsequent genetic manipulations.

The specification teaches methods of 'rejuvenating' a senescent cell via nuclear transfer. The claims rely heavily on the art to support genetic modification of isolated primary cells and nuclear transfer in various mammalian species. Such methods of genetic modification and nuclear transfer were relatively new at the time of filing but

within the realm of routine experimentation. However, without guidance from the specification, it cannot be discerned the precise methodology needed to carry out the methods as claimed. For example, "between genetic manipulations, using nuclear transfer" is so vague that in light of the lack of specific teachings in the specification, it is not enabled..

With regard to claim 23, the claim recites that the method of claim 21 results in an embryonic cell that has telomeres at least as long on average as a same age control embryonic cell. However, no cell is isolated or no end point containing an embryonic cell is recited.

With regard to claim 25, the claim refers to "the cell resulting from the nuclear transfer" however, no cell is ever isolated from any embryo or other entity that might form from a nuclear transfer unit. The cell that results from nuclear transfer is a nuclear transfer unit, the nucleus of which is not necessarily joined or reprogrammed. Additionally, claim 25 encompasses any type of genetic modification to non-fibroblast donors because it fails to require that subsequent round fo NT be carried out with a fibroblast isolated from the product of the previous round of NT (see below under #4).

The claims also recite transfer of chromosomes from the primary cell to an enucleated oocyte. This aspect of the claims is not enabled as it reads on transfer of less than a full complement of chromosomes and chromosomes lacking other nuclear factors that are necessary to reconstitute an enucleated oocyte.

Claims 21-24,25,27-28 and 106 encompass primate mammals and are subject to the same enablement considerations as set forth above under the scope of enablement rejection #2 for claims 1,3,4,6-8,11,-12,14-16.

Claims 29-36 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the claimed method using a) non-primate, mammalian b) fibroblasts and c) any a genetic modification that does not require homologous recombination, does not reasonably provide enablement for the claimed method using any mammalian cells other than a) non-primate mammalian b) fibroblasts wherein c) any genetic modification requiring homologous recombination is made. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

a) The claims encompass use of nuclear transfer animals or embryos that are primate mammals. The specification and art at the time of filing fails to enable such methods for primates for reasons set forth above under #2.

b) The claims encompass use of non-fibroblasts cells in the claimed methods. This requires use of non-fibroblasts as donors wherein the cells are taken to senescence or near senescence prior to NT.

c) The claims also encompass performing homologous recombination in any cell type prior to using the cell for NT. The claims also encompass genetic manipulation of blastocyst cells and ICM cells as well as terminally differentiated cells that are not dividing. The specification has provided no guidance with regard to genetic modification of these cell types.

Applicant has argued in previous prosecution (12/07/2009) that homologous recombination is merely an inoperable embodiment and is not specifically recited in the claims. Furthermore, Applicant has argued that the claims fail to require genetic modification at senescence but it can occur prior to driving the cells to senescence.

The specification teaches use of sensescent or near-senescent adult and fetal fibroblast cells, i.e. they have completed 90-95% of their lifespan with less than 2-3 population doublings remaining, in nuclear transfer. The only donor cells that were genetically modified in the specification were fetal fibroblasts and a transgene was randomly inserted into the genome (page 29).

Homologous recombination is not merely an inoperable embodiment but is an entire class of genetic modification equal to genetic insertions. As well, while the first genetic modification in the methods is generally limited to being performed in a fibroblast, which has a significant enough numbers of population doublings to perform genetic modification, subsequent cloning steps are not so limited.

The state of the art at the time of filing held that no primary cell had a sufficient number of population doublings left in their life span to perform homologous recombination followed by nuclear transfer. Additionally, only fetal fibroblasts had been

genetically modified at all, i.e. random transgene insertion, with enough lifespan left for effective nuclear transfer (see Schnieke, 1997, **Science**, 278:2130-2133; Cibelli, 1998, **Science**, 280:1256-1258, specifically, page 1256, col. 2, paragraph 1). Denning taught that primary cells have limited proliferation capacity and any genetic modifications and nuclear transfer must be accomplished prior to senescence [**Cloning and Stem Cells**, 3:221-231, 2001, specifically refer to page 222, col. 1, lines 5-8] [see also, Clark, **Transgenic Research**, 2000, 9:263-275]. In a study of sheep and goat primary somatic cells, Denning found that of primary somatic cells, fibroblasts were the only cells that either grew at all from the primary cell source or has sufficient population doublings for the selection required in targeted gene transfer. Sheep primary cell cultures primarily were composed of fibroblasts after the third passage or about 12 doublings (Denning, page 224, col. 2, lines 11-13). In a similar analysis of pig primary cultures, fibroblasts, as in the sheep study, became the predominant cell-type after three passages, but, unlike sheep, pig fibroblasts underwent a crisis after 40 population doublings and had an unstable karyotype (Denning, page 224, col. 2, parag. 4 line 4 to page 225, col. 1, line 8). Additional studies of cell cultures prepared from fetal pig organs (gut, kidney, lung and mesonephros) showed that these cells senesced or entered crisis after even fewer doublings than the fibroblast cultures (page 225, col. 1-2, bridg. sent.). The art further taught at the time of filing, that the even if sufficient population doublings could be achieved for selection, many of the pure sheep targeted clones senesced before they could be expanded for nuclear transfer, meaning that targeting frequency was lower than expected (page 228, col. 1-2, bridg. sent.). Similar experiments in pigs

demonstrated that all the clones senesced, and no targeted cells for nuclear transfer were obtained. Therefore, the claims are not enabled so far as they require genetic modification in culture that is demonstrated by the art to drive the cells to a senescent state to the extent that they are no longer effective in completing the nuclear transfer process.

For these reasons, all donor cells of the claims should be limited to fibroblast, not just the initial donor cell used in the first round of nuclear transfer.

Claim Rejections - 35 USC § 112-2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 27-28 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 27 recites the limitation "the re-clone" in line 13. There is insufficient antecedent basis for this limitation in the claim. Claim 28 depends from claim 27.

Claim 24 is unclear. The claim is drawn to a mammalian primary cell produced according to the method of claim 21. However, it is not clear what primary cell is produced by the method of claim 21. Claim 21 begins with an isolated fibroblast that is used in nuclear transfer. No primary cell is isolated as a product of the method of claim 21.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-25,29-31,35 and 36 rejected under 35 U.S.C. 102(b) as being anticipated by Cibelli (Science, 1998,280,1256-1258).

Claims 21-25, 29-31, 35 and 36 are drawn to methods of making multiple genetic modifications be successive rounds of nuclear transfer.

Cibelli teaches performing compound genetic manipulations using fetal fibroblast cells from a cow. A fetal fibroblast cell was transfected with a transgene and taken to senescence in culture (page 1258). The nearly senescent cell was used in NT to form a 40 day fetus, from which new, genetically altered fetal fibroblasts were obtained and found to have been 'rejuvenated' with 30 population doublings remaining. Cibelli taught that these cells could then be used for additional genetic modification through successive rounds of nuclear transfer as claimed. This rejection is not in conflict with the enablement rejection set forth above. The enablement rejection is on the grounds that the claim is not complete and enabled as written. However, Cibelli meets the limitations of the claims as written.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 15 is rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Auerbach (Cancer Research, 1987, 1492-1496).

Claim 15 is directed to a cell isolated by the method of claim 8 wherein claim 8 results in isolation of a cell from a teratoma.

Claim 15 is a product by process claim in which the process of isolating the cell carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (an isolated cell) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed isolated cell are met by any isolated cell in the prior art. Patentability of a product-by-

process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

Auerbach taught isolated cells and cells isolated from a teratoma.

Thus, the teachings of Auerbach anticipate the limitations of claim 15.

Claims 15 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Vandenburgh (1996, Human Gene Therapy, 7, 2195-2200).

Claim 15 is directed to a cell isolated by the method of claim 8 wherein claim 8 results in isolation of a cell from a teratoma. Claim 16 is drawn to a tissue comprising cells isolate by the method of claim 11.

Claims 15 and 16 are product by process claims in which the process of isolating the cell carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (an isolated cell or a tissue comprising an isolated cell) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed isolated cell or tissue comprising an isolated cell are met by any isolated cell in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without

consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

Vandenburgh taught engineering murine skeletal muscle tissue using isolated myoblasts.

Thus, the teachings of Vandenburgh anticipate the limitations of claims 15 and 16.

Claim 24 is rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Scappaticci (Hum Genet, 1982, 62:16-24).

Claim 24 is directed to a mammalian primary cell produced according to the method of claim 21. The only patentable weight imparted on claim 24 by claim 21 is that the primary cell be a fibroblast.

Claim 24 is a product by process claim in which the process of producing the cell carries little patentable weight. It is only the product, which is anticipated by the prior art and not the process by which the product was made. This is because the final product (an isolated cell) is not distinguished by any particular features or characteristics resulting from the process by which it is made. As such, the limitations of the claimed cell are met by any primary fibroblast cell in the prior art. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re* Thorpe, 227 USPQ 964 (Fed. Cir. 1985).

Scappaticci taught mammalian primary fibroblast cells.

Thus, the teachings of Scappaticci anticipate the limitations of claim 24.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VALARIE BERTOGLIO whose telephone number is (571)272-0725. The examiner can normally be reached on Mon-Fri 6:30-2:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Valarie Bertoglio/
Primary Examiner, Art Unit 1632